UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,702	04/15/2002	Camilo Anthony Leo Selwyn Colaco	8830-24	7592

23973 7590 12/07/2009

DRINKER BIDDLE & REATH
ATTN: INTELLECTUAL PROPERTY GROUP
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER	
GRASER, JENNIFER E	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
12/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/049,702	COLACO, CAMILO ANTHONY LEO SELWYN	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/12/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-11 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-11 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Acknowledgment and entry of the Amendment submitted on 8/12/09 is made. Claims 8-11 and 14-16 are currently pending.

Applicants' arguments and claim amendments have obviated the former 112, 2nd paragraph rejection, the Obviousness-type double patenting rejection and the 102 rejection of Laminet and Wallen.

Claim Rejections - 35 USC § 112-Written Description

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 8-11 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Written support could not be found for the new limitation:
'"eliciting both a cytotoxic and an antibody based immune response" Applicants have pointed to page 14, lines 8-17, of the specification for support. This passage recites:

In order to determine the immunogenicity of the SP complexes, T cell proliferation assays may be used. Suitable assays include the mixed-lymphocyte reaction (MLR), assayed by tritiated thymidine uptake, and cytotoxicity assays to determine the release of 51Cr from target cells, see 'Current Protocols in

Immunology', Wiley Interscience, 1997. Alternatively, antibody production may be examined, using standard immunoassays or plaque-analysis assays, or assessed by intrauterine protection of a foetus, see ~Current Protocols in Immunology'.

It is noted that nowhere in this passage does it state or provide results that the claimed compositions elicit both types of immune responses. The passage mrely recites assay used to assess the type of immune response raised. Applicants should point to specific support for the limitation by page and line number or remove it from the claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 8-11 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Srivastava et al (WO 95/24923).

Srivastava et al disclose vaccines and compositions comprising stress protein-peptide complexes. They specifically teach heat shock proteins (HSP) may be used as the stress protein. Srivastava et al define ‘stress protein’ as a protein whose intracellular concentration increases when exposed to stressful stimuli, is capable of binding to other proteins or peptides, and is capable of releasing the bound proteins in the presence of ATP or low pH. See page 10, lines 9-13. Srivastava et al define stressful stimuli to

"include, but [are] not limited to, heat shock, nutrient deprivation, metabolic disruption, oxygen radicals, and infection with intracellular pathogens". See page 10, lines 13-15. Srivastava et al teach that they have discovered that a stress protein-peptide complex when isolated from a eukaryotic cell infected with a preselected intracellular pathogen and then administered to a mammal can stimulate a cytotoxic T cell response directed against cells infected with the same pathogen. See page 19, lines 1-9. Srivastava et al teach that the stress proteins can accumulate to very high levels in stressed cells, but they occur low to moderate levels in cells that have not been stressed. They give the example of Hsp70 which is hardly detectable at normal temperatures but becomes one of the most actively synthesized proteins in the cell upon heat shock and Hsp90 and Hsp60 are abundant at normal temperatures in almost all mammalian cells, but are even further induced at by heat. See bottom of page 23. Srivastava et al teach that their immunogenic stress protein-peptide complexes may include any complex containing a stress protein and a peptide that is capable of inducing an immune response in a mammal. See page 23, lines 20-27. The complexes can be prepared from cells infected with an intracellular pathogen as well as cells that have been transformed by an intracellular pathogen. See page 24, lines 5-10. Pages 46-48 teach that adjuvants and/or pharmaceutically carriers may be used. Page 13, lines 1-15 teach that the complexes may be infected with bacterial, protozoal or parasitic intracellular organisms. Claim 15 specifically recites the 'stress' to be subjection to tumor necrosis factor. However, this is a product-by-process claim (as are all of the claims), "The patentability of a product does not depend upon its method of production. If the product

in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). There does not appear to be a structural difference between the product claimed and the product taught by the prior art, e.g., the claimed compositions solely comprise an immunogenic determinant any complex comprising a stress protein and an antigenic peptide fragment. Srivastava et al teach that their immunogenic stress protein-peptide complexes may include any complex containing a stress protein and a peptide that is capable of inducing an immune response in a mammal. See page 23, lines 20-27. Srivastava et al specifically teach the complexes can be prepared from cells infected with an intracellular pathogen as well as cells that have been transformed by an intracellular pathogen. See page 24, lines 5-10.

5. Claims 8-11 and 14-16 remain rejected under 35 U.S.C. 102(e) as being anticipated by Srivastava et al (US 5,961,979).

Srivastava teaches a vaccine composition comprising an immunogenic determinant comprising one or complexes between a shock protein and an antigenic peptide from the heat stressing of a cell infected with a bacterial, protozoal or parasitic

intra-cellular pathogen (see title, abstract and claims). Srivastava teaches that a vaccine containing a stress protein peptide complex when isolated from cells infected with an intracellular pathogen and then administered to a mammal can effectively stimulate immune response against the pathogen (see column 4, line 60-68 summary of the invention). Srivastava teaches bacteria and protozoa (see column 7, lines 1-15). Srivastava teaches pharmaceutical carriers including aqueous composition and adjuvants (see column 23, lines 19-68). Srivastava teaches a method of producing the stress proteins including heat shock proteins and complex vaccine (see columns 5, 13 and 14). The prior art teaches the claimed invention. . Claim 15 specifically recites the 'stress' to be subjection to tumor necrosis factor. However, this is a product-by-process claim (as are all of the claims), "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). There does not appear to be a structural difference between the product claimed and the product taught by the prior art, e.g., the claimed compositions solely comprise an immunogenic

determinant any complex comprising a stress protein and an antigenic peptide fragment.

Response to applicant's arguments:

Applicants' arguments address both Srivastava patents so they will be addressed together. These arguments have been fully and carefully considered but are not deemed persuasive. Applicants argue that Strivastava describe stress peptide complexes purified to homogeneity. They argue that, accordingly, these complexes can comprise only a single stress protein species. They quote page 28, line 20, of WO 95/24923 "the Hsp-70-peptide complex can be purified to apparent homogeneity using this method". These arguments are not commensurate in scope with the claimed invention. The claims do not require the use of more than one stress peptide. In fact the claims recite the complex is between a stress induced protein [not plural] and an antigenic determinant. Strivastava state that the complex "can" be purified to homogeneity but do not require it.

Applicants also argue that their complexes are capable of eliciting both cell-mediated CTL responses as well as humoral antibody response as evidenced by the passage at page 14, lines 8-17, of the specification for support. This passage recites:

In order to determine the immunogenicity of the SP complexes, T cell proliferation assays may be used. Suitable assays include the mixed-lymphocyte reaction (MLR), assayed by tritiated thymidine uptake, and cytotoxicity assays to determine the release of 51Cr from target cells, see 'Current Protocols in Immunology', Wiley Interscience, 1997. Alternatively, antibody production may be examined, using standard immunoassays or plaque-analysis assays, or assessed by intrauterine protection of a foetus, see ~Current Protocols in Immunology'.

It is noted that nowhere in this passage does it state or provide results that the claimed compositions elicit both types of immune responses. The passage merely recites assay used to assess the type of immune response raised. Applicants should point to specific support for the limitation by page and line number or remove it from the claims.

Additionally, the instant claims recite 'an immunogenic determinant comprising any induced stress protein and any antigenic peptide *obtained* from, a cell which has been infected with….". Srivastava et al teach an immunogenic determinant comprising any induced stress protein and any antigenic peptide. The claims are product-by-process claims. "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). There does not appear to be a structural difference between the product claimed and the product taught by the prior art, e.g., the claimed compositions solely comprise an immunogenic determinant any complex comprising a stress protein and an antigenic peptide fragment. While a specific stressor may cause more stress protein and stress protein complexes to be induced, it does not appear to change the structure of the complex, nor

does the claim require a specific level of complex. Srivastava et al do not solely teach constitutively expressed complexes. Srivastava discloses the claimed compositions produced by a stress process and isolated from natural sources, produced in situ. The bacterial heat shock protein (see Table 1 and definitions) is complexed together with an antigenic peptide fragment from a bacteria (see col. 7, line 7 "Chlamydia"), fungus, or protozoa, wherein the heat shock protein complex is isolated from natural sources (see col. 21, line 28). Accordingly, Srivastava et al anticipates the claimed compositions.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

2/4/09